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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,040	11/21/2006	Bin Wang	WANG0002-100	5612

34132 7590 04/07/2009

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
04/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,040	WANG ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-12 and 20-35* is/are pending in the application.

4a) Of the above claim(s) *22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 9-12, 19-21, 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and remarks, filed on 1/21/2009, are acknowledged. Claims 1, 9-12, and 20-22 are amended. Claims 2-8 and 19 are cancelled. New claims 30-35 are added. Claims 1, 9-12, and 20-35 are pending. Claims 22-29 are withdrawn as being drawn to nonelected inventions. Claims 1, 9-12, 19-21, and 30-35 are currently under examination.

Objections Withdrawn

The objection to the drawings, because the originally submitted drawings were blank, is withdrawn in light of applicant's amendment thereto.

The objection to the specification for the use of the trademarks TWEEN and PROGRAF is withdrawn in light of applicant's amendment thereto.

Rejections Withdrawn

Claims 1-12 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "a targeted nucleic acid vaccine," is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1 and 5-6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "active polypeptide from a targeted antigen," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "targeted pathogen nucleic acid vaccine," is withdrawn in light of applicant's amendment thereto.

The rejection of claims 2, 5, and 7 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "comprises a single package or a mixture," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said targeted antigen that is encoded by said nucleic acid vaccine is 2:1 to 10:1," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said targeted antigen that is encoded by said nucleic acid vaccine is 5:1," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine is 1:5 to 5:1," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein the proportion of the inactivated targeted pathogen and the targeted pathogen nucleic acid vaccine is 1:2 to 1:10," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 10, because there is insufficient antecedent basis for the limitation "said nucleic acid vaccine," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "wherein said eukaryote cell expression vector is a plasmid, virus, bacteriophage," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 20, because there is insufficient antecedent basis for the limitation "said nucleic acid vaccine," is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 5, 9-12, and 20-21, under 35 U.S.C. 102(b) as being anticipated by Wen *et al.* (US Patent 6,221,664, 4/2001), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 5, 7, 9-12, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pundi *et al.* (WO 02/078732 A1, 10/2002), is withdrawn in light of applicant's amendment thereto.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10-12, 20, and newly submitted claims 30-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, and 11 of copending Application No. 11/644,435, for the reasons set forth in the previous office action in the rejection of claims 1-6, 10-12, and 20.

Applicant argues:

That there is no basis to reject the claims for double patenting because no claims in either application have been allowed.

Applicant's arguments have been fully considered and deemed non-persuasive.

According to MPEP 804:

Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott,* 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau,* 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Therefore, the rejection is proper and is maintained.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 11/644,435 are drawn to a composition comprising a eukaryotic cell expression vector containing nucleotide sequences encoding an allergenic protein or a polypeptide that comprises an antigenic epitope of said allergenic protein and the protein or polypeptide that comprises an antigenic epitope of said protein. Said vector comprises an RSV, CMV, or SV40 promoter and the vector is in proportion to the protein in a ratio of 1:5 to 5:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9-12, 20-21, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen *et al.* (US Patent 6,221,664, 4/2001), for the reasons set forth in the rejection of claims 1-6, 9-12, and 20-21 in the previous office action.

Applicant argues:

1. That the Wen reference is teaching away from the instant invention. Applicant asserts that one of skill in the art would read the Wen reference as teaching compositions that enhance

or induce a T-cell immune response, as opposed to a composition that is effective to inhibit a T-cell immune response.

2. That the combination of references does not yield the present invention because the ratios recited in the claims are not found in the references and the references do not suggest or teach modifying the reference to yield the present invention. Applicant argues that even if the references were combined, they would not yield a T-cell immune response inhibitor comprising the elements recited in the claims in the ratios recited.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, first, the compositions disclosed by Wen meet the structural limitations of the instant claims. Unless applicant is asserting that the claims lack written description and enablement, there is no reason to believe that a composition that meets the structural limitations of the claims does not have the function applicant asserts. Second, the claims require that the composition inhibit *a* T-cell immune response. They do not specify which T-cell immune response. There are a very large number of responses and activities that T-cells carry out and there are multiple types of T-cells. Immune responses are generally characterized by either a Th1 or Th2 response. Whichever of these occurs, the functions of the other type are inhibited. In column 3, Wen states that interferon-γ was increased by administration of the composition. Interferon-γ inhibits the proliferation of Th2 cells. Therefore, the compositions of Wen inhibit *a* T-cell immune response.

Regarding argument 2, the prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be "so great as to render the [claim] nonobvious to one reasonably skilled in the art."*Id.* In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. See 35 U.S.C. 103(a). Factors other than the disclosures of the cited prior art may provide a

basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. The only difference between the prior art disclosure and the instant invention is that the prior art does not specifically disclose the ratio of nucleic acid to protein they used. Differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical.

As outlined previously, the instant claims are drawn to T-cell immune response inhibitors that comprise a nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine, where the proportion of the nucleic acid vaccine and the targeted antigen is 2:1 to 10:1, or is 5:1, or the proportion of the nucleic acid vaccine and the active polypeptide from the targeted antigen is 1:5 to 5:1. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter.

Wen *et al.* disclose a vaccine comprising hepatitis B surface antigen as well as plasmid DNA which encodes said antigen and an adjuvant (see column 5, lines 1-26). The plasmid contains a CMV promoter (column 3, line 14).

Wen *et al.* differs from the instant invention in that specific proportions are not disclosed.

However, it would have been obvious to one of ordinary skill in the art, at the time of invention, to choose any of the claimed proportions because differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical.

Claims 1, 9-12, 19-21, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pundi *et al.* (WO 02/078732 A1, 10/2002) for the reasons set forth in the rejection of claims 1-12 and 19-21 in the previous office action.

Applicant argues:

1. That the Pundi reference is teaching away from the instant invention. Applicant asserts that one of skill in teh art would read the Pundi reference as teaching compositions that enhance or induce a T-cell immune response, as opposed to a composition that is effective to inhibit a T-cell immune response.

2. That the combination of references does not yield the present invention because the ratios recited in the claims are not found in the references and the references do not suggest or teach modifying the reference to yield the present invention. Applicant argues that even if the references were combined, they would not yield a T-cell immune response inhibitor comprising the elements recited in the claims in the ratios recited.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, first, the compositions disclosed by Pundi meet the structural limitations of the instant claims. Unless applicant is asserting that the claims lack written description and enablement, there is no reason to believe that a composition that meets the structural limitations of the claims does not have the function applicant asserts. Second, the claims require that the composition inhibit *a* T-cell immune response. They do not specify which T-cell immune response. There are a very large number of responses and activities that T-cells carry out and there are multiple types of T-cells. Immune responses are generally characterized by either a Th1 or Th2 response. Whichever of these occurs, the functions of the other type are inhibited. If the response is a Th1-type, interferon-γ will be increased by administration of the composition. Interferon-γ inhibits the proliferation of Th2 cells. If the response is a Th2-type, IL-10 will be increased. IL-10 inhibits activation and effector functions of T cells. Therefore, the compositions of Pundi inhibit *a* T-cell immune response.

Regarding argument 2, the prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be "so great as to render the [claim] nonobvious to one reasonably skilled in the art."*Id.* In determining obviousness, neither the particular motivation to make the claimed invention nor the

problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. See 35 U.S.C. 103(a). Factors other than the disclosures of the cited prior art may provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. The only difference between the prior art disclosure and the instant invention is that the prior art does not specifically disclose the ratio of nucleic acid to protein they used. Differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical.

As outlined previously, the instant claims are drawn to T-cell immune response inhibitors that comprise a nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine, where the proportion of the nucleic acid vaccine and the targeted antigen is 2:1 to 10:1, or is 5:1, or the proportion of the nucleic acid vaccine and the active polypeptide from the targeted antigen is 1:5 to 5:1. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter.

Pundi *et al.* disclose a vaccine formulation comprising a DNA vaccine that encodes a polypeptide of a virus as well as the inactivated virus (see abstract). The DNA vaccine includes a CMV promoter and the composition can also include an adjuvant (see pages 7-8).

Pundi *et al.* differs from the instant invention in that specific proportions are not disclosed.

However, it would have been obvious to one of ordinary skill in the art, at the time of invention, to choose any of the claimed proportions because differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical. Furthermore, Pundi *et al.* state that the quantity of inactivated virus in the vaccine can vary widely depending on the immunogenicity and potency of the formulation (see page 5, lines 27-31).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645